Charles M. Palmer **Director** 

## **INFORMATIONAL LETTER NO.1203**

DATE: January 3, 2013

TO: Iowa Medicaid Physicians, Advanced Registered Nurse Practitioners,

Certified Nurse Midwives, Hospitals, Clinics, Maternal Health Centers,

and Family Planning Agencies

**ISSUED BY:** Iowa Department of Human Services, Iowa Medicaid Enterprise (IME)

RE: 17-Alpha Hydroxyprogesterone Caproate

**EFFECTIVE: Immediately** 

17-alpha hydroxyprogesterone caproate (17HP) is a synthetic steroid hormone medication. It is an evidence-based treatment indicated to reduce the risk of preterm delivery during pregnancies in which the mother has a history of a previous spontaneous preterm delivery. It is indicated only for singleton pregnancy and contraindicated in certain high-risk pregnancies. It is given by a weekly injection of 250 mg intramuscular (IM) weekly beginning at 16 weeks gestational age and continuing until delivery or until the pregnancy reaches 37 weeks. Use of hydroxyprogesterone in those high-risk pregnancies meeting the criteria above is indicated and would constitute the standard of care.

There are currently two forms of 17HP available. The first is a compounded version and has been payable by Iowa Medicaid for a number of years. The other version is the FDAapproved version known as Makena. The IME has finalized its coverage and payment policy for Makena. The compounded version has not previously required prior authorization (PA) by the IME and will continue to not require a PA. Makena does require a PA.

The use of Makena is covered under Iowa Medicaid Prior Authorization when **ALL** of the following PA criteria have been met:

- 1. The member is between 16 weeks and 0 days and 36 weeks 6 days gestation with a singleton pregnancy; and,
- 2. The member has a prior history of preterm delivery before 37 weeks gestation; and,
- 3. The member does **not** have current or history of thrombosis or thromboembolic disorders, known or suspected breast cancer, other hormone-sensitive cancer, or history of undiagnosed abnormal vaginal bleeding unrelated to pregnancy, cholestatic jaundice of pregnancy, liver tumors, benign or malignant, or active liver disease or uncontrolled hypertension; and
- 4. No other form of progesterone, already covered/payable under Pharmacy Point Of Sale (POS) is appropriate (e.g., progesterone suppositories) as a "preferred" product on the Preferred Drug List (PDL); and,

- 5. There are medical contraindications to the member receiving the compounded version, 17 alpha-hydroxyprogesterone caproate, instead of Makena **or** the compounded version of 17P is not readily available/accessible.
- 6. Treatment should begin between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
- 7. Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.
- 8. No more than 20 doses (16 weeks gestation to 36 weeks gestation) will be approved.

17HP is covered as a physician-administered medication under the Iowa Medicaid medical benefit, since it is a physician-administered drug. As such, it is not covered under the "pharmacy" benefit. Claims submitted by pharmacies at the point of service will be denied as the IME Pharmacy POS system does not cover 17HP in any form.

For coverage of the compounded 17HP, providers will need to obtain the medicine from a licensed compounding pharmacy. The provider administers the medication and submits a claim to the IME. The claim must contain the appropriate "J" code, as follows:

- For the compounded version of 17P, providers should bill J2675 (per 2012 HCPCS Level II manual, use this code for Gesterone, Gestrin, per 50mg; this code can also be used for compounded 17P) and the correct/applicable NDC number.
- For Makena, providers should use J1725 (per 2012 HCPCS Level II manual, this code is to be used for Makena, per 1mg)

If there are any questions about filing claims for 17HP, please contact the IME Provider Services Unit at 1-800-338-7909, or locally in Des Moines at 515-256-4609 or email at <a href="mailto:imeproviderservices@dhs.state.ia.us">imeproviderservices@dhs.state.ia.us</a>.